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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,588	10/15/2002	Leszek Wojnowski	VOS-31	7619

7590 08/23/2004

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EXAMINER	
CHANDRA, GYAN	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 08/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,588	WOJNOWSKI ET AL.	
	Examiner	Art Unit	
	Gyan Chandra	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-37* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The examiner has interpreted claim 28 to be dependent from claim 27.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-8, 34, 36-37, in part, drawn to a polynucleotide having the nucleic acid sequence of SEQ ID NO: 56, a vector comprising the SEQ ID NO: 56 and a host cell with the vector comprising polynucleotide SEQ ID NO: 56, and method of making a protein.

Group 2, claim(s) 9, drawn to a method of making a hPXR protein.

Groups 3-69, claims 1-8, 34, 36-37 in part, drawn to a polynucleotide having the nucleic acid sequence of SEQ ID NOS: 57,60... 177, a vector comprising the SEQ ID NOS: 57, 58....177, and a host cell with the vector comprising polynucleotide SEQ ID NOS: 57, 58 ....177, and method of making proteins from polynucleotide comprising SEQ ID NOS: 57, 58... 177.

Groups 70 – 136, claim(s) 9, drawn to a hPXR protein encoded by the polynucleotide of SEQ ID NOS: 57, 58....177.

Groups 137-204, claim(s) 10-11 and 36 –37, in part, drawn to an antibody that binds to hPXR encoded by a polynucleotide of SEQ ID NOS: 56, 57...177.

Groups 205-272, claim(s) 12-14, drawn to the transgenic non-human animals comprising DNA vector having one polynucleotide of SEQ ID NOS: 56, 57...177.

Groups 273-340, claim(s) 15-16, drawn to a method of identifying and obtaining an hPXR inhibitor by a method of detecting signals in a cell line and in a transgenic non-human animal.

Groups 341-408, claim(s) 17-21, drawn to a method of identifying and obtaining an inhibitor capable of modulating the activity of a molecular variant of the hPXR gene product.

Groups 409-476, claim(s) 22-24, drawn to a method of diagnosing the hPXR susceptibility disorder in a subject.

Groups 477-544, claim(s) 25, drawn to a method of treatment by administering a medicament to a subject.

Groups 545-612, claim(s) 26, drawn to a method of treatment by introducing a functional wild type hPXR gene into cells.

Groups 613-680, claim(s) 27-29, and 36-37, in part, drawn to a method of production of medicament composition comprising drug or prodrug of inhibitor to the hPXR.

Groups 681-748, claim(s) 30-31, drawn to an inhibitor, which binds the hPXR protein or a fragment thereof.

Groups 749-816, claim(s) 32-33, and 36-37, in part, drawn to use of a DNA oligonucleotide for genotyping hPXR alleles in a subject.

Groups 817-884, claim(s) 35, drawn to use of an antibody for the detection of protein from hPXR and its variants.

The inventions listed as Groups 1-885 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

A. Claim(s) 1-8, 34, 36-37 are anticipated by prior art. Hillier, et.al. (The WashU-Merk EST project, Accession number H85558.1; GI : 1064633, 14 November 1995), teach a polynucleotide sequence comprising SEQ ID NO: 56 of the instant application. (Please see nucleic acids from 1-11 of SEQ ID NO: 56 of the instant application and nucleic acids 33-43 of Hillier et.al.)

B. Groups 3-69, recite the technical feature of polynucleotide sequence having SEQ ID NO: 57, 60...177, which are not required by the other product Groups.

C. Groups 70-136, recite the technical feature of a protein encoded by polynucleotide sequence having SEQ ID: 57, 60....177, which are not required by the other product Groups.

D. Groups 137-204 recite the technical feature of an antibody which recognizes an epitope of amino acid sequence of claim 2, which is not required by the other product Groups.

E. Groups 205-272 recite the technical feature of a transgenic animal comprising at least one polynucleotide of claim 1, which is not required by the other product Groups.

F. Groups 273-340 recite the technical feature of contacting the protein with a compound to be screened in the presence of components that provide a signal and detecting the presence or absence of signal in a transgenic non-human animal, which is not required by the other method Groups.

G. Groups 341-408 recite the technical feature of contacting the protein with a molecule known to bind the protein and then contacting the complex with a compound to be screened, which is not required by the other method Groups.

H. Groups 409- 476 recite the technical feature of the methods of diagnosing a hPXR susceptibility disorder in a subject which is not required by the other method Groups.

I. Groups 477-544 recite the technical feature of the methods of treatment by administering the medicament comprising a polynucleotide of Claim 1, which is not required by the other method Groups.

J. Groups 545-612 recites the technical feature of the methods of treatment by introducing a functional wild type hPXR gene into cells in a subject, which is not required by the other method Groups.

K. Groups 613-680 recite the technical feature of a method of production of medicament comprising an inhibitor of the hPXR, which is not required by the other method Groups

L. Groups 681-748 recite the technical feature of an inhibitor which binds the hPXR protein or a fragment of hPXR, which is not required by the other product Groups.

M. Groups 749-816 recite the technical feature of using DNA oligonucleotide for genotyping hPXR alleles in a subject, which is not required by the other method Groups.

N. Groups 817-884 recite the technical feature of a use of an antibody for hPXR or its variants for purpose of detecting the hPXR protein level, which is not required by the other method Groups.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their separate search requirements, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571)272-2922. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

Gyan Chandra
AU 1646
9 August, 2004